DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 15-24 and 43-57, 59-66, 68-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan '348 in view of Mariant '027, along with Phelps '259.

Kaplan discloses in figures 1-6C a device for treating an enlarging body lumens that anticipates a device for occluding a body lumen passageway comprising a tubular member 4, having a first end and a second end (fig. 1A), one end is open (1B), a lumen extending therein 12, to the open end, which is expandable in the body lumen from a first configuration with a first transverse dimension to a second larger configuration with a second larger dimension (col. 3, lines 11-16), the tubular member includes an open framework structure (the openings in the tubular member provide an open framework), a fibrous member (14, 16), made of polymeric material (col. 11, lines 18-21), fibrous member is woven strands (col. 7, lines 30-33), of biocompatible material (col. 11, lines 18-20), connected to the tubular member (fig. 1B), the fibrous material is disposed within the lumen (fig. 1B), in a plurality of section (fig. 1A), at a first end (fig. 1A), the tubular member is made of stainless steel (col. 5, lines 10-14), the tubular member

includes anchoring members (col. 5, lines 48-50), to secure the tubular member to the walls of a body lumen, the tubular member expands from a first configuration to a second larger configuration by release of radially compressive force, the tubular member is formed of a superelastic material (col. 3, lines 11-15), the second configuration of the tubular member has a radially expandable diameter which increase along at least a section thereof from the first end of the tubular member to the second end of the tubular member (col. 3, lines 11-16), the tubular member has a lattice framework (2A), the lattice framework is thin-walled metallic tube having a pattern of cuts 10, along the tubular member, the framework includes a braid of wire (a helical strand woven into the tubular member, col. 3, lines 23-26), helical coil (col. 5, lines 55-58), the tubular member is configure to promote tissue growth (col. 7, lines 52-66), capable of provoking an inflammatory response (col. 8, lines 55-58), through copper (which is old and well known in the art), the inflammatory material is radioactive (col. 5, lines 18-21) and the tubule member has an open wall structure (fig. 1A). However, Kaplan doesn't disclose the fibrous material being bundled strands. Mariant teaches in figures 1-6 an occlusion device comprising fibers 12 that are in bundles (col. 5, lines 12-16) and the fibers permit tissue growth (col. 5, lines 45-51). It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the fibers as taught by Mariant could be substituted for the fibers disclosed by Kaplan in order to permit tissue growth into the tubular member. The fibers could be bundles as taught by Kaplan. The fibrous material is porous (nylon) as taught by Mariant. The fibrous material can be coated to promote tissue growth and the transverse dimensions

of the strands is a design choice. Phelps teaches in figures 1-6C a fibrous member that is a mesh 130. The fibrous mesh as taught by Phelps could be used to allow for tissue ingrowth from the wall of the reproductive body lumen into the fibrous mesh member around and inside of the tubular open framework to occlude a body lumen. The mesh member can be located within the tubular member as taught by Phelps. The device could be used to permanently occlude the reproductive body lumen. The device could be used to prevent the passage of reproductive cells through the lumen. The fibrous members as taught by Mariant are made of nylon and Dacron which are permeable materials. Phelps teaches the mesh being longitudinally disposed along at least a section of an outer surface of the tubular member.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims above, and further in view of Phelps '259.

Phelps '259 teaches in figures 1-5an occluding device comprising a plug attached to fibers (col. 3, lines 15-20). The plug is capable of provoking inflammatory response. It would have been obvious to one having ordinary skill in the art at the time that the invention was made that the plug as taught by Phelps could be used to provide an inflammatory response to stimulate tissue growth, while at the same time occluding the fallopian tube.

Claims 28-33 and 35-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan in view Mariant, along with Phelps.

Kaplan discloses in figures 1-6C a device for treating body lumens that anticipates a contraceptive, substantially as claimed, as set forth above. Mariant teaches in figures

1-6 an occluding device comprising fibers to promote tissue growth. Phelps teaches in figures 1-5 fibers formed as a mesh. It would have been obvious to one having ordinary skill in the art at the time that the invention that the fibers as taught by Mariant could be formed as a mesh as taught by Phelps in order to allow tissue growth in the lumen and around the tubular member. Note: Kaplan discloses a catheter (col. 10, lines 35-38) used to insert the tubular member.

Response to Arguments

Applicant's arguments filed February 4, 2008 have been fully considered but they are not persuasive. Applicant argues that the examiner didn't respond to previous arguments that were submitted on December 12, 2007. However, the examiner did read the arguments hoping that applicant had included new patentable structural limitations that would make the claims allowable over the prior art. However, since the arguments didn't include any persuasive arguments the examiner didn't respond to the arguments. Applicant argues Kaplan is used for preventing restenosis of dilated body lumens, such as blood vessels. The examiner concurs. However, the main concept that must be decided by the examiner is can Kaplan perform the function of occluding a fallopian tube. The first issue is whether Kaplan discloses inserting the tubular open framework member into the fallopian tube. Kaplan discloses that the tubular open framework member can be inserted into the fallopian tube (col. 9, lines 25-28), for other clinical situations. The second issue is whether the tubular member having an open framework is capable of allowing tissue ingrowth. Clearly the open framework will permit tissue to grow into the tubular member. Thus, Kaplan not only discloses

inserting the tubular member into the fallopian tube but one of ordinary skill in the art would recognize that tissue could grow into the tubular member through the open framework. Also the fibers (14, 16), are made of the same material as the fibers in the present invention that used to promote tissue ingrowth. Kaplan may teach how to prevent occlusion but Kaplan is capable of performing occlusion. The claims are patentable because the invention is able to perform a function that the prior art doesn't disclose or suggest. Also if the prior art is capable of performing the same function as the present invention than the claims of the present invention aren't patentable over the prior art. Applicant argues that Kaplan doesn't disclose a tubular member that promotes epithelialization or endothelization. However, any tubular member with an open framework that is inserted into a lumen will promote endothelization (the growing of tissue). Applicant argues that there is no motivation to modify the filament disclosed by Kaplan with the fibers as taught by Mariant. However, Kaplan disclosed fibers that are made of a material (nylon or Dacron) that promotes tissue growth. On the other hand, Mariant was used to provide a teaching that the two material (nylon and Dacron) promote tissue ingrowth. Many times when making an argument the examiner doesn't provide a teaching (in this case, nylon and Dacron promote tissue growth) that a material can perform a specific function. Thus, Mariant was used to provide a teaching that nylon and Dacron (both disclosed by Kaplan and Mariant and the disclosure of the present invention) are materials that promote tissue ingrowth. Thus, the tissue ingrowth would be used to assist in occluding the fallopian tube. Applicant argues that the combination of Phelps with Kaplan and Mariant would destroy the function of

Kaplan. However, Phelps was used as a modifier to provide the fibers in a mesh to increase tissue growth inside and outside of the tubular member. Thus, the tubular member disclosed by Kaplan can be used as an occluder to prevent sperm from entering the fallopian tube. The fibers would promote tissue ingrowth to hold the tubular member in place.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BROWN whose telephone number is (571)272-4972. The examiner can normally be reached on 5:30 am-4:00 pm Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Brown/
Primary Examiner, Art Unit 3772